

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number **20-676**

CHEMISTRY REVIEW(S)

M E M O R A N D U M



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Drug Evaluation & Research

Date: April 26, 1996

From: David B. Katague, Ph.D

To: NDA 20-676 File

Subject: Vagistat-1 (tioconazole 6.5%) Vaginal Ointment

On November 10, 1995, Bristol-Myers Products submitted a supplemental application to NDA 19-355 for over-the-counter marketing of Vagistat Vaginal Ointment for the treatment of vulvovaginal candidiasis. For administrative and tracking purposes, the supplement has been converted to a new NDA 20-676.

The CMC section of this NDA is the same as NDA 19-355 which was approved on December, 1986. There are no changes in the formulation, specifications, analytical methods, manufacturing and packaging procedures.

Please refer to the above mentioned NDA for CMC information and review. A new chemist's review is not required.

David B. Katague, Ph.D.
Review Chemist

Concurrence:
HFD-830/SBRoy/Team Leader

[Signature]
4/26/96



Memorandum

Date • October 2, 1996

From David B. Katague, Ph.D.
Review Chemist, HFD-520

Subject Vagistat-1 (tioconazole) Vaginal Ointment, 6.5%
Change of Marketing Status from Rx to OTC

To NDA 20-676 File:

The CMC section of this NDA is the same as the approved NDA 19-355. There is no change in the formulation, specifications, analytical methods, manufacturing or packaging procedures. Please refer to NDA 19-355 for CMC reviews. A new chemist's review is not required.

David B. Katague, Ph.D.
Review Chemist

Concurrence:

HFD-830 BBDunn/Deputy Director, DNDClIII

BBDunn
10/3/96

**APPEARS THIS WAY
ON ORIGINAL**

Memorandum

Date • October 2, 1996

From David B. Katague, Ph.D.
Review Chemist, HFD-520

Subject Vagistat-1 (tioconazole) Vaginal Ointment, 6.5%
Change of Marketing Status from Rx to OTC

To NDA 20-676 File:

The CMC section of this NDA is the same as the approved NDA 19-355. There is no change in the formulation, specifications, analytical methods, manufacturing or packaging procedures. Please refer to NDA 19-355 for CMC reviews. A new chemist's review is not required.

David B. Katague, Ph.D.
Review Chemist

Concurrence:

HFD-830 BBDunn/Deputy Director, DNDCIII

BBDunn
10/3/96

**APPEARS THIS WAY
ON ORIGINAL**